

This Page Is Inserted by IFW Operations  
and is not a part of the Official Record

## **BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

**IMAGES ARE BEST AVAILABLE COPY.**

As rescanning documents *will not* correct images,  
please do not report the images to the  
**Image Problem Mailbox.**



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/647,309	01/03/2001	Christine Andreoni	PF82PCTSEQ/d	7033

25666 7590 02/11/2003

THE FIRM OF HUESCHEN AND SAGE  
500 COLUMBIA PLAZA  
350 EAST MICHIGAN AVENUE  
KALAMAZOO, MI 49007

EXAMINER
----------

SHAHNAN SHAH, KHATOL S

ART UNIT	PAPER NUMBER
----------	--------------

1645

13

DATE MAILED: 02/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

File copy

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/647,309	ANDREONI ET AL.
	Examiner Khatol S Shahnan-Shah	Art Unit 1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on 04 April 2002.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 1-40 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) \_\_\_\_\_ is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) 1-40 are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:  
1. Certified copies of the priority documents have been received.  
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_ .  
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)  
3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ . 6) Other: \_\_\_\_\_ .

**DETAILED ACTION**

1. The Examiner of U.S. Patent application SN 09/647,309 has changed. In order to expedite the correlation of papers with the application please direct all future correspondence to Examiner Shahnan-Shah, Technology Center 1600, Art Unit 1645.
2. Applicants' response to notice to comply and submission of substitute sequence listing in paper form and computer readable form received 4/3/2002, paper # 11 is acknowledged. CRF is good and entered in the database.
3. Applicants' response to election and amendment received 4/3/2002, paper # 11 is acknowledged. Claims 25 and 32 were amended.
4. Claims 1-40 are pending and under consideration in this application.

***Election/Restrictions***

5. Applicants' election with traverse of 4/3/2002, paper # 11 is acknowledged. Applicants elected with traverse, to prosecute the invention of Group "a", and more specifically an antigen. The traversal is on the ground that the present application is a national stage application of PCT/FR98/03814 filed under 35 USC 371. Therefore PCT Rule 13 regarding "unity of invention" applies.

In view of applicants arguments and amendments to claims and sequence listing a new lack of unity follows:

6. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-20 are drawn to use of an enterobacterium membrane protein OmpA as a nasal composition.

Group II, claim(s) 21 and 40 are drawn to a method for renaturation of a protein obtained by recombinant process.

Group III, claim(s) 22-39 are drawn to use of bacterial membrane protein as a nasal composition.

7. The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The special technical feature linking group I-III appears to be use of bacterial membrane protein fragment for the preparation of a pharmaceutical composition for improving immunity intended to be administered nasally.

However, Rauly et al. (Research in Immunology Vol. 149, No: 1, pp. 99, Jan 1998) and Erdile et al. (Vaccine, Vol. 15, No: 9, pp. 988-995, June 1997) teach use of bacterial membrane protein fragment for the preparation of a pharmaceutical composition for improving immunity intended to be administered nasally (see the entire documents).

Therefore, the technical feature linking the inventions of groups I- III does not constitute a special technical feature as defined by the PCT Rule 13.2, as it does not define a contribution over the prior art.

Furthermore as set forth above, each of group I-III has a special technical feature that is not

required for the other groups.

8. Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

*Election*

9. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

a- If applicants elect group I, then there are additional election of species.

Please choose one of the species an antigen or a hapten from claims 1- 2, 7-9, 11-15 and 17-19.

Please choose one of the species virus or bacterium from claims 8, 10 and 11.

Please choose one of the species of SEQ ID # from claims 6 and 13.

b- If applicants elect group II, then there are additional election of species.

Please choose one of the species of detergent from claims 21 and 40.

c- If applicants elect group III, then there are additional election of species.

Please choose one of the species an antigen or a hapten from claims 22, 26-28, 30-35 and 37-38.

Please choose one of the species virus or bacterium from claims 29-31.

Please choose one of the species of SEQ ID # from claims 25, 32 and 33.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

The species are shown to be distinct because they are drawn to a plurality of disclosed patentably distinct products comprising structurally and functionally distinct molecules and activities.

Applicants are required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic: 1, 2, 21, 22 and 40.

**Note:** In order to expedite prosecuting the application based on compact prosecution the following corrections are requested.

***Priority***

**10.** Complete priority statement is missing from specification:

This application filed under former 37 CFR 1.62 lacks the necessary reference to the prior application(s). A statement reading, " This is a U.S.C. 371 of Application of PCT/FR99/00703 filed on March 26,1999 and claims priority to French application No. 98/03814, filed on March 27, 1998" should be entered following the title of the invention or as the first sentence of the specification. Also, the current status of the parent nonprovisional application(s) should be included.

Should applicants desire to obtain the benefit of foreign priority under 35 U.S.C. 119(a)-(d) prior to declaration of an interference, a translation of the foreign application No. 98/03814 should be submitted under 37 CFR 1.55 in reply to this action.

***Abstract***

**11.** This application does not contain an abstract of the disclosure as required by 37 FR 1.72(b). An abstract on a separate sheet is required.

***Drawings***

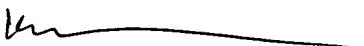
**12.** The drawings are objected to by the Draftsperson under 37 CFR 1.84 or 1.152. See attached form PTO 948.

***Conclusion***

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol S Shahnan-Shah whose telephone number is (703) 308-8896. The examiner can normally be reached on 7:30am-4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F Smith can be reached on (703) 308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Khatol Shahnan-Shah, BS, Pharm, MS

Biotechnology Patent Examiner

Art Unit 1645

February 4, 2003

  
LYNETTE F. SMITH  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600